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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/507,931	04/28/2005	Andrew Butterworth	STHP-018	5683
24353 7590 12/21/2007 BOZICEVIC, FIELD & FRANCIS LLP 1900 UNIVERSITY AVENUE SUITE 200 EAST PALO ALTO, CA 94303			EXAMINER APANIUS, MICHAEL	
			ART UNIT 3736	PAPER NUMBER
			MAIL DATE 12/21/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

### Application No.

10/507,931

### Applicant(s)

BUTTERWORTH, ANDREW

### Examiner

Michael Apanius

### Art Unit

3736

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 20 April 2007.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 September 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/20/2007 has been entered. The amendment to claim 1 and the addition of new claim 22 is acknowledged.

### ***Drawings***

2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: "latch 28" (page 10, lines 6-7). Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the

applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

### ***Claim Objections***

3. Claims objected to because of the following informalities:
  - a. At claim 2, it appears that "the signal" lacks proper antecedent basis in the claim.
  - b. At claim 2, it appears that "the group comprising" should be --the group consisting of--.
  - c. At claim 2, it appears that "the movement" should simply be --movement--.
  - d. At claim 2, it appears that "the release" should simply be --release--.
  - e. At claim 8, it appears that "the container" lacks proper antecedent basis.

Claim 5 recites a container. However, claim 8 only depends upon claim 1.

Appropriate correction is required.

### ***Claim Rejections - 35 USC § 101***

4. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

5. Claims 16-18 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under

35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

***Claim Rejections - 35 USC § 112***

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 5-8, 12 and 13 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claim 1 recites, "means to store temperature data generated by the temperature sensing means." Although a means to store temperature data appears to be enabled for the embodiment having electronic temperature sensing means (see paragraph bridging columns 7 and 8 in the specification), it does not appear that a means to store temperature data is enabled for the embodiments defined in claims 5-8, 12 and 13. Applicant does not describe how a means to store temperature data would obtain the temperature data from the temperature sensing embodiments set forth in claims 5-8, 12 and 13. Therefore, the subject matter of claims 5-8, 12 and 13 is not described in such a way as to enable one skilled in the art to make and/or use the invention.

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 16-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

10. Claims 16-18 provide for the use of an indwelling thermometer, but, since the claims do not set forth any steps involved in the method/process, it is unclear what methods/processes applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

***Claim Rejections - 35 USC § 102***

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. Claims 1, 2, 9-11 and 14-22 are rejected under 35 U.S.C. 102(b) as being anticipated by Zartman (US 4,651,137). Zartman discloses a vaginal indwelling thermometer in which the thermometer comprises temperature sensing means (column 9, lines 33-35), and signal means (column 9, lines 56-59) for providing a continued indication that a predetermined threshold body temperature has been exceeded

(column 11, lines 40-59), integral with means to store temperature data (data storage means are required to calculate average values across multiple days; column 10, lines 46-57) generated by the temperature sensing means and which signal means provides a mechanical indication (an audible signal can be considered a mechanical indication) that the temperature has been exceeded, wherein said vaginal indwelling thermometer is configured to be left in a vagina of a subject for a long period of time without causing discomfort to said subject and without being easily lost (column 7, lines 38-39). The signal means activates a buzzer. The data relates to temperatures above and below the threshold. The threshold is determined by a computer program (column 10, lines 38-53) contained within the thermometer (paragraph bridging columns 11 and 12). Zartman discloses a series of thermometers (column 12, lines 19-20) having a different predetermined threshold temperature across a range of temperatures from 35-45 degrees Celsius (the threshold temperatures will be different because they are implanted in different animals among different species). The use of the thermometer includes insertion (figure 3) into a vagina of a subject mammal, including human females (column 8, lines 3-6), allowing the thermometer to indwell, and periodically observing the signal means. In regards to new claim 22, the thermometer is fully capable of being left in a vagina for at least one complete menstrual cycle.

***Claim Rejections - 35 USC § 103***

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

14. Claims 3-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zartman (US 4,651,137) in view of Newhall (US 3,889,658). Although Zartman discloses that the temperature sensing means are known in the prior art, Zartman does not expressly disclose the type of temperature sensing means. Zartman does not expressly disclose an enclosed hollow container comprising two chambers separated by a waisted portion of the container or the further limitations of claims 6-8. Newhall teaches a thermometer (figure 3) having an enclosed hollow container comprising two chambers (19, 24) separated by a waisted portion (16). The wasted portion of the container contains a temperature sensing means (41) and one chamber includes a marker dye (27). The temperature sensing plug may be a wax (column 6, line 26) having a melting point close to a predetermined threshold temperature (column 7, lines 3-7). Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to have applied temperature sensing means as taught by Newhall wherein the thermometer comprises a container having two chambers in the thermometer of Zartman to achieve the predictable result of sensing temperature in a body.

15. Claims 12 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zartman (US 4,651,137) in view of Inoue et al. (US 4,154,106). Although Zartman discloses that the thermometer is formed of a plastics material (column 8, lines 43-45),



Zartman does not expressly disclose a thermochromatic pigment/ink or fixative. Inoue teaches an irreversible color change (column 7, lines 19-32) which can be considered a thermochromatic pigment/ink and fixative. Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to have used an irreversible color change as taught by Inoue in the thermometer of Zartman in order to achieve the predictable result of measuring body temperature in a body.

### ***Response to Arguments***

16. Applicant's arguments with respect to the amended claims have been considered but are moot in view of the new ground(s) of rejection.

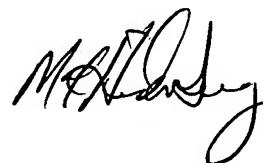
### ***Conclusion***

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Apanius whose telephone number is (571) 272-5537. The examiner can normally be reached on Mon-Fri 8am-4:30pm.

18. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

19. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MA

A handwritten signature in black ink, appearing to be "M. J. [unclear]", located in the lower right quadrant of the page.